510(k) Summary of Substantial Equivalence

Proprietary Name:	Placer™ Model 6232 Steerable Stylet
Common Name:	Steerable Stylet
Device Classification:	Class II
Product Classification and Code:	Stylet, Catheter (74 DRB)
Classification Panel:	Circulatory System Devices Panel
Establishment Registration Number:	2127690
Contact Person:	Mike Johnson Product Regulation Manager Medtronic, Inc. 4000 Lexington Avenue North Mail Stop: X260 Shoreview, MN 55126-2983 Telephone: (612) 514-9835 Facsimile: (612) 514-9954 E-mail: *mike.johnson@medtronic.com*

Performance Standard

Performance standards do not currently exist for these devices. None established under Section 514.

Device Description

The Medtronic Placer Model 6232 Steerable Stylet consists of a shaft with a distal, shapeable portion. At the proximal end of the steerable stylet is a handle featuring a "spinner" mechanism that allows shaping of the stylet without removing, manually shaping, and reinserting the stylet.

When the Medtronic Placer Model 6232 Steerable Stylet is inserted in a lead, the steerable stylet forms a continuously variable J-shape with a curvature up to 180° as the spinner handle is turned. In more flexible leads, the curvature may result in a shape up to 270°.

The Placer Model 6232 Steerable Stylet will be made commercially available in three (3) shaft lengths for 45, 52, and 58cm leads. These are common lengths of straight Medtronic transvenous leads.

The Placer Model 6232 Steerable Stylet will be sterilized using a gamma radiation process and is intended for single use.

Indications for Use

The Medtronic Placer Model 6232 Steerable Stylet is a lead implantation tool designed for single-handed operation. When inserted into the lead lumen, the Placer Model 6232 Steerable assists in implantation of straight Medtronic right

atrial and right ventricular transvenous leads which accept a 0.016" stylet. The steerable stylet is intended for single use only.

Substantially Equivalent Devices

The Medtronic Placer Model 6232 Steerable Stylet is believed to be substantially equivalent to the following predicate devices currently in interstate commerce with respect to comparable features, materials of construction and intended use.

- Locator™ Steerable Stylet – Manufactured by Pacesetter, Sylmar, CA (K972814)
- NAVIPORT™ Deflectable Tip Guiding Catheter – Manufactured by Cardima, Fremont, CA (K974683)
- Marinr™ Series EP Diagnostic Catheter – Manufactured by Medtronic CardioRhythm, Minneapolis, MN (K951347)

Labeling, packaging and sterilization of the Placer Model 6232 Steerable Stylet is substantially equivalent to that of the predicate devices listed above.

Summary of Studies

Medtronic, Inc. performed device integrity testing to support that the Medtronic Placer Model 6232 Steerable Stylet is equivalent to the predicate devices. Device integrity testing included visual, functional and joint tensile strength. All device integrity test results for the Placer Model 6232 Steerable Stylet met specified requirements.

Conclusion (Statement of Equivalence)

Through data and information presented, numerous similarities support a determination of substantial equivalence, and therefore market clearance of the Medtronic Placer Model 6232 Steerable Stylet through this 510(k) Pre-Market Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 2000

Mr. Mike Johnson
Product Regulation Manager
Medtronic, Inc.
7000 Central Avenue NE
Minneapolis, MN 55432-3576

Re: K000955
Trade Name: Medtronic Placer™ Model 6232 Steerable Stylet
Regulatory Class: Class II
Product Code: DRB
Dated: March 23, 2000
Received: March 24, 2000

Dear Mr. Johnson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): **K000955**

Device Name: **Medtronic Placer™ Model 6232 Steerable Stylet**

Indications For Use: When inserted into the lumen of a lead, the Placer Model 6232 Steerable Stylet assists in implantation of straight Medtronic right atrial and right ventricular transvenous leads which accept a 0.016" stylet.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)